MAR 1 1 2004

EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Matsushita Electric Works, Ltd.
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Date Summary Prepared: December 15, 2003

2. Name of the Device:

Panasonic Wrist Blood Pressure Monitor, Models EW 3031/EW 3032

3. Predicate Device Information:

The Panasonic Wrist Blood Pressure Monitor, Models 3031/3032 are substantially equivalent to the MECA Blood Pressure Meter, Model EW 243/254, K991458.

4. Device Description:

The Panasonic Wrist Blood Pressure Monitor, Models 3031/3032 are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

5. Intended Use:

The Panasonic Oscillometric Wrist Blood Pressure Monitors, Models EW3031 and EW 3032 are devices intended to measure systolic and diastolic blood

pressure rate of an adult individual by using a pressurized cuff on the left wrist. The devices are not intended for use on infants or children. The devices are designed for home use only and not for ambulatory measurements.

6. **Comparison to Predicate Devices:**

Both devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. A wrist cuff is inflated automatically; deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Each device uses a similar capacitance-type pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined each unit operates a solenoid valve to release the pressure to zero. Our Wrist Blood Pressure Monitor, Model EW 3031/3032 , differs from the predicate device in the cuff application part, display function, and memory function.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.
The following testing was conducted:

a. Reliability Test - Operation Conditions
b. Reliability Test - Drop Testing
c. Reliability Test - Storage
d. Reliability Test - Vibrating Testing
e. EMC Test
f. IEC 60601-1 Safety Test
g. Evaluation of Pulse Rate Measurement

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Panasonic Wrist Blood Pressure Monitor, Models 3031/3032 tested met all relevant requirements of the aforementioned tests.

8. **Discussion of Clinical Tests Performed:**

ANSI/AAMI SP10-1992 "National Standard for Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The EW 3031 and EW 3032 met all relevant requirements of this standard.

9. Conclusions:

We have demonstrated that the Panasonic Model EW 3031 and EW 3032 areas safe and effective as the predicate based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2004

Matsushita Electric Works, Ltd.
c/o Ms. Carolann Kotula
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K033894
Trade Name: Panasonic Wrist Blood Pressure Monitor, Models EW 3031 and EW 3032
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 12, 2004
Received: February 13, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033894/5

Exhibit B

510(k) Number (if known): K033894

Device Name: Panasonic Wrist Blood Pressure Monitor, Models EW 3031 and EW 3032

Indications For Use: The Panasonic Wrist Blood Pressure Monitor, Models EW 3031 and EW 3032 are devices intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

For the EW 3032, display of Normal (green), Prehypertensive (yellow) or Hypertensive (orange) are based on blood pressure values classified in the paper: "JNC Express, The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" , U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Pressure Institute, National High Blood Pressure Education Program, NIH Publication No 03-5233, May 2003. The display values are generally known, but not proven, to be an indicator of your blood pressure.

The EW 3032 is not intended to be a diagnostic device. Contact your physician if prehypertensive or hypertensive values are indicated.

Prescription Use ____ **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** X **(Optional Format 1-2-96)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033894